NOVABONE
SYNTHETIC BONE GRAFT PRODUCTS

K080009

510(k) Summary **12/31/07**

NovaBone Putty – Bioactive Synthetic Graft

MAY - 6 2008

1. Submitter Information:

Name:	NovaBone Products, LLC
Address:	13709 Progress Boulevard, #33 Alachua, FL 32615
Telephone:	(386) 462-7660
Facsimile:	(386) 418-1636
Contact:	David M. Gaisser

2. Name of Device:

Trade Name:	NovaBone Putty – Bioactive Synthetic Graft
Common Name:	Osteoconductive Bone Void Filler Synthetic Resorbable Bone Graft Material
Regulation Number:	21 CFR 888.3045
Regulation Name:	Bone Void Filler

3. Legally Marketed Predicate Device:

Predicate #1:	NovaBone Putty – Bioactive Synthetic Graft - [K060728]
Predicate #2:	NovaBone – Resorbable Bone Graft Substitute - [K021336, K052494]

4. Device Description

NovaBone Putty is an osteoconductive, bioactive, bone void filler device. It is composed of a calcium-phosphorus-sodium-silicate (Bioglass) particulate mixed with a synthetic binder that acts as a temporary binding agent for the particulate. The particulate and binder are provided premixed as a pliable cohesive material. On implantation, the binder is absorbed to permit tissue infiltration between the Bioglass particles. The particles are slowly absorbed and replaced by new bone tissue during the healing process.

5. Intended Use

NovaBone Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

NovaBone Putty is not indicated for use in load-bearing applications. It does not possess sufficient mechanical strength to support load-bearing defects prior to hard tissue ingrowth. It should not be used for vertebroplasty or kyphoplasty

procedures. In cases of fracture fixation or where load support is required, standard internal or external stabilization techniques must be followed to obtain rigid stabilization in all planes. NovaBone Putty must not be used to gain screw purchase or to stabilize screw placement.

6. Technological Characteristics

The technological characteristics of the NovaBone Putty device are identical to the NovaBone Putty device cleared per K060728, which are in turn similar to those of the NovaBone predicate. The device and predicates are designed as osteoconductive space-filling devices to be gently packed into defect sites and used as non-structural scaffolds for the body's natural healing and bone regeneration process. The device indications are the same as for the predicates. The device is intended to be used alone, or in combination with autogenous bone.

The primary component of NovaBone Putty is identical to the bioactive glass (45S5 Bioglass) particulate found in the NovaBone predicate. This synthetic material is both biocompatible and osteoconductive. The NovaBone Putty includes a synthetic binder as an inert carrier for ease of handling and delivery, forming a premixed cohesive material. The binder is biocompatible and is absorbed after implantation, opening space between the bioactive glass particles for cell infiltration and bone formation. The bioactive glass particulate remains for a longer post-implantation period, acting as a scaffold for bone ingrowth. This particulate is absorbed and replaced by new bone tissue. Animal testing has demonstrated that the majority of the material is absorbed within six months of implantation, with >98% of the material being absorbed by 12 months. The timeframe for full absorption in humans has not been determined, but is expected to be at least 12 months.

7. Warnings and Precautions

NovaBone Putty is not indicated for use in load-bearing applications. It should not be used for vertebroplasty or kyphoplasty procedures. NovaBone Putty is intended for use by clinicians familiar with bone grafting and internal/external fixation techniques. In cases of fracture fixation or where load support is required, standard internal or external stabilization techniques must be followed to obtain rigid stabilization in all planes. NovaBone Putty must not be used to gain screw purchase or to stabilize screw placement.

NovaBone Putty is intended for manual application and is not intended for injection. Injection of NovaBone Putty should not be conducted as it could result in device over-pressurization, which may lead to device extrusion beyond the intended application site or to embolization of fat or the device into the bloodstream.

8. Complications

Possible complications are the same as to be expected of autogenous bone grafting procedures. These may include: superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, delayed union, loss of reduction, failure of fusion, loss of bone graft, graft protrusion and / or dislodgement, and general complications that may arise from anesthesia and / or surgery.

9. Conclusion

NovaBone Putty is claimed to be substantially equivalent to the NovaBone Putty and NovaBone (particulate) predicate devices as a non-structural osteoconductive bone void filler for osseous defects. *In vivo* performance data were presented in support of the requested expansion of device claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NovaBone Products, LLC
% Mr. David M. Gaisser
13709 Progress Boulevard, #33
Alachua, FL 32615

MAY - 6 2008

Re: K080009
Trade/Device Name: NovaBone Putty-Bioactive Synthetic Graft
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: December 31, 2007
Received: February 27, 2008

Dear Mr. Gaisser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: NovaBone Putty – Bioactive Synthetic Graft

Indications For Use:

NovaBone Putty – Bioactive Synthetic Graft is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

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Prescription Use XX OR (Per 21 CFR 801.109) Over-The-Counter Use_____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080009